IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CIE, BAYER PHARMA AG and BAYER HEALTHCARE PHARMACEUTICALS INC., Plaintiffs, v. WATSON LABORATORIES, INC., Defendant.	C.A. No. 13-978 (RGA) REDACTED - PUBLIC VERSION
MERCK & CIE, BAYER PHARMA AG and BAYER HEALTHCARE PHARMACEUTICALS INC., Plaintiffs, v. WATSON LABORATORIES, INC., Defendant.	C.A. No. 13-1272 (RGA) REDACTED - PUBLIC VERSION

PLAINTIFFS' POST-TRIAL RESPONSE BRIEF

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INTRODUCTION

Merck invented the Type I crystal form of calcium 5-methyl-(6S)-tetrahydrofolate (Metafolin®) through an unusual chemical procedure of a high temperature salt formation followed by a high temperature slurry. Claim 4 of U.S. Patent No. 6,441,168 (DTX2, the "'168 Patent") covers this form, which is used in Bayer's Beyaz® and Safyral® oral contraceptives on which Watson has filed ANDAs. Watson's challenge to the validity of Claim 4 is two-fold—the commercial § 102 (b) on-sale bar allegations and the technical defenses of anticipation, obviousness and written description. Despite the sharp substantive divide between these two halves of the case, Watson's approach is similarly flawed. For both, Watson ignores critical evidence.

In connection with the alleged on-sale bar, Watson provides no response to PTX94, the Weider e-mail that shows that neither Weider nor Merck believed that any binding offer or contract for the sale of 2kg of Metafolin® ever existed. Watson also gives short shrift to the unanimous testimony that Weider and Merck shared an understanding that no legal obligations could arise without a formal contract signed by both parties. Watson instead focuses on the irrelevancy of whether in 2015 the witnesses all remembered where that understanding came from.

It came from § 5.2 of the CDA. The contemporaneous documents and the testimony are all consistent with the operation of § 5.2, which protected Weider and Merck from any legal obligation until there was a "definitive agreement … signed by both parties." DTX65 at 4. Watson's brief offers up its thoughts on why § 5.2 does not apply to this case—thoughts it never shared during the trial. Every one of Watson's arguments is the result of a back-to-front approach, wherein first Watson decides that Merck made legally binding offers and then reverse-engineers the contrary evidence, contorts the language of § 5.2, and ignores the testimony of all the witnesses to support those conclusions. But the CDA came first and § 5.2 set the rules of the road for the negotiations. Without a legally binding offer and without a legally binding contract for sale, there is no invalidity

case here; and Watson has failed to meet its burden.

On the technical side of the case, Watson conspicuously omits any discussion of Dr. Marsden's testimony. Dr. Marsden, Watson's own expert, opined that the starting material for Watson's key experiment was contaminated by the very invention in this case—the Type I crystal. That experiment was also based on a Watson proprietary process and not the prior art. But Dr. Marsden's testimony is not all Watson ignores. Watson chooses not to address the unrebutted testimony that the "practically insoluble" product of U.S. Patent No. 5,350,850 (the "'850 Patent"), which Watson represents to the Court *is* the Type I crystal, is in fact one hundred times less soluble than the Type I crystal. And Watson also refuses to acknowledge what U.S. patent law dictates—the '850 Patent product is what the law calls a "paper" or "prophetic example." Watson's expert based his opinion on the mistaken view that the '850 Patent has "real data" in it. As a matter of law it does not. That is why when Plaintiffs attempted to reproduce the actual '850 Patent Example 3 it did not work. It is a paper example untested by the inventors and not enabled. Watson could have done the experiment the '850 Patent outlined and found out the same thing, but instead chose to do its own seeded and flawed non-prior art exercise. And Watson relies exclusively on that flawed exercise to argue that the Type I crystal is obvious. An exercise about which Dr. Marsden told the truth before Watson attacked him.

Watson fares no better with its written description argument. The '168 Patent need not disclose examples of every embodiment within the scope of Claim 4. Watson's expert found himself simultaneously arguing that the skilled person reading the patent would know both that Claim 4 was limited to the Type I crystal and that the Type I crystal could not be a monohydrate. But somehow he concluded the same skilled person would believe Claim 4 lacked written description because the '168 Patent must describe this impossible monohydrate. The proposition refutes itself.

Watson failed to meet its burden to prove that Claim 4 is invalid.

ARGUMENT

I. CLAIM 4 IS NOT INVALID UNDER THE ON-SALE BAR

For a patent to be invalid under the on-sale bar, the invention must be the subject of a commercial offer for sale more than one year prior to the U.S. application date for the patent. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998). An offer is invalidating if it "rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance." *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1048 (Fed. Cir. 2001). Under the law of the Federal Circuit, this Court should look to the general law of contract, not the law of any specific state, in deciding whether an offer for sale or sale took place. *Grp. One*, 254 F.3d at 1048.

Watson implies in its brief that its burden of proof is not clear and convincing evidence. Def. Br. 6-7. This is incorrect. The cases Watson cites for this proposition, *TP Laboratories*, *Inc. v. Professional Positioners, Inc.*, 724 F.2d 965 (Fed. Cir. 1984) and *Leader Technologies, Inc. v. Facebook, Inc.*, 770 F. Supp. 2d 686 (D. Del. 2011), examine how the experimental use exception to the statutory on-sale bar interacts with the burden of clear and convincing evidence. This case is not about an experimental use exception and *TP Labs.* and *Leader Technologies* are inapplicable. *See Lisle Corp. v. A.J. Mfg. Co.*, 398 F.3d 1306, 1316 (Fed. Cir. 2005) (holding that *TP Labs.* was about the experimental use exception and that it did not alter Federal Circuit precedent that the burden never shifts to the patent owner). Watson must prove that there was a sale or offer for sale by clear and convincing evidence. Watson cannot meet that burden because it has built a case based on a backwards looking and piecemeal approach to the evidence.

Parties have the right to contract and define their relationships without being forced into surprise obligations. *Adjustrite Sys., Inc. v. GAB Bus. Servs., Inc.*, 145 F.3d 543, 548 (2d Cir. 1998). Watson revises the history between the parties in order to support its theory that a sale was made between Merck and Weider. To do so, Watson must first interpret the evidence without even

discussing the contract that Merck and Weider used to control their interactions, the confidentiality and nondisclosure agreement ("CDA"). Then, Watson tortures the plain language of the CDA to try to make its vision of an on-sale bar reality. Specifically, Watson argues that the CDA did not cover the discussions in September 1998 because a transfer of 2kg (62 million doses) is not a "transaction" or, alternatively, that the phrase "definitive agreement … signed by both parties" (DTX65 at 4) should be construed to include separate documents not signed by anyone. Finally, having lain silent throughout trial and never discussed this in its putative summary judgment brief or anywhere else, Watson now contends that Merck waived application of the CDA. Watson cannot carry its burden of clear and convincing evidence under any of its theories.

Plaintiffs will start where the parties did, with the CDA.

A. There Was No Sale Or Offer For Sale In September 1998 And The CDA Covered All Discussions From February 1998 Forward

Merck and Weider were aware of the CDA in 1998. It was mutually drafted and negotiated by their representatives. Section 5.2 renders any negotiations or agreements short of a "definitive agreement … signed by both parties" without legal effect. DTX65 at 4. "A manifestation of willingness to enter into a bargain is not an offer if the person to whom it is addressed knows or has reason to know that the person making it does not intend to conclude a bargain until he has made a further manifestation of assent." Restatement (Second) of Contracts § 26 (1981). Section 5.2 set the ground rules for the parties' further discussions and was never abandoned or modified. Thus, without a contract signed by both Merck and Weider, there can be no legally binding offer or sale.

1. The evidence must be viewed in light of the CDA—a negotiated document governing all of Merck's and Weider's interactions

Merck and Weider first contemplated a potential strategic partnership in late 1997 in order to give Merck access to the dietary supplements industry in the United States. TT714:10-18, 715:23-716:18 (Buchholz). Early in the discussions, on December 8, 1997, Dr. Herwig Buchholz of Merck

suggested to Dr. Luke Bucci of Weider that they enter into a CDA in order to have "more detailed discussions." DTX63. Merck and Weider signed the CDA in February 1998. TT724:7-9; DTX65. As Dr. Bucci testified, the CDA was not boilerplate. TT209:24-210:8. It was the subject of discussions, drafts, and input by both parties. TT725:3-14 (Buchholz). The CDA included § 5.2:

> Unless and until such definitive agreement regarding a transaction between Weider and Merck has been signed by both parties, neither party will be under any legal obligation of any kind with respect to such a transaction.

DTX65 at 4. As Dr. Buchholz testified, § 5.2 meant that "the conversations and discussions" between Merck and Weider did not create any obligation unless and until they both "signed a formal agreement and contract." TT728:4-14.

Dr. Bucci of Weider testified that it was also his understanding at the time that until Weider and Merck had a signed agreement, "it was all discussions."

> Q: Did you have an understanding of whether this meant that neither party could be bound by your negotiations and discussions until you had a signed contract?
>
> A: That ***was*** my understanding, is that until we had a signed agreement, it was all discussions.

TT213:3-9 (emphasis added). Watson makes much of Dr. Bucci's other testimony that he did not recall seeing the Martin faxes or § 5.2 of the CDA before his deposition. Def. Br. 16. But what Dr. Bucci did testify about was his 1998 understanding that there were no legal obligations between Merck and Weider without a signed agreement. When he saw § 5.2 of the CDA, Dr. Bucci interpreted it just like everyone else in this case (other than Watson) and linked that present-day interpretation to his 1998 understanding.

Watson offers no answer to Dr. Buchholz and Dr. Bucci's unrebutted testimony that in 1998 Merck (Buchholz) and Weider (Bucci) were in agreement that there could be no legal obligations between them without a signed agreement. Section 5.2 is the source of that shared understanding,

whether or not Dr. Bucci remembered the section number or even having seen it—he remembered his understanding. Watson cannot meet its burden of proof by relying on 17 years of elapsed time to defocus the inquiry away from the only governing contract between Merck and Weider (the CDA) and inserting its own views of the correspondence that remains.

The CDA applied to Merck and Weider's discussions in the fall of 1998. TT213:23-214:13 (Bucci). Dr. Buchholz and Dr. Roland Martin testified that Merck would have never had conversations with a potential partner without a governing confidentiality agreement in place. TT91:2-11 (Martin), 726:8-16 (Buchholz). It was simply "too dangerous." TT91:10-11 (Martin). Thus, Watson had to concede that the CDA was still in effect even through January 1999:

> THE COURT: All right. And just while I'm asking a question, too, do you agree that the CDA remained in effect at least through January, when the 9th and 11th, when the question of buying metafolin was finally resolved?
>
> MR. MADDOX: Yes.

TT794:9-15. With the CDA in place, Watson must find a "definitive agreement … signed by both parties" in order to prevail. It cannot.

2. There is no "definitive agreement … signed by both parties"

In order for Merck and Weider to be under any legal obligation towards each other, as § 5.2, Dr. Buchholz, and Dr. Bucci unanimously attest, there must be a "definitive agreement … signed by both parties." DTX65 at 4. There is no such document, and despite twice ambiguously promising to show one, Watson failed to do so at trial. TT22:17-20 (Watson says "the writings that constituted the sale are in fact signed by both parties"), 792:14-19 (Watson again tries to say there are signatures). When pressed, Watson admitted that it relies on an e-mail in lieu of actual signatures.

> THE COURT: What did you say constituted the signatures under the relevant contract?
>
> MR. MADDOX: Well, they weren't literally signed. They were e-mailed signature.

TT792:24-793:4. Watson never returned to this subject and continues to obfuscate whether there is any such signed agreement (there is not). Def. Br. 15 (referring generically to "signed, exchanged faxes"). Watson still never identifies one document that is a "definitive agreement … signed by both parties" even if its 2015-based view of what is a "signature" were correct, which it is not.[1]

The remaining evidence introduced at trial, including the documentary record, was consistent with the testimony regarding Merck and Weider's shared understanding. Watson's inability to explain or even address that evidence shows how incorrect Watson's version of events is.

3. The trial evidence showed that neither Merck nor Weider believed there was a legally binding offer or a contract for sale

Merck and Weider discussed the development of Metafolin® over a period of 15 months. Both were sophisticated large corporations. Consistent with § 5.2 and with the unchallenged testimony of Drs. Bucci and Buchholz, there is no evidence that either party believed there was a contract or legal offer for the sale of Metafolin®, much less clear and convincing evidence of one.

No sale to Weider was possible in the fall of 1998 because hurdles to such a sale remained, which Merck and Weider discussed and understood. For example, Drs. Buchholz and Bucci testified that there were a number of tests to perform and issues to resolve before either company could accept or use Metafolin®, including toxicology tests that Dr. Buchholz testified without challenge were not complete until years later. TT733:3-737:19 (Buchholz), 218:21-219:6 (Bucci).

[1] Putting aside the question of whether an e-mail response is a "signature" within the meaning of the 1998 CDA, Watson's efforts here also seek to take advantage of 17 years of advancement in business communications. Precisely because electronic signatures were widely viewed as not legally binding in 1998—the dawn of the business e-mail era—Congress passed the E-Sign Act, 15 U.S.C. §§ 7001-7006, to preempt that understanding. The E-Sign Act was effective on October 1, 2000.

Dr. Martin further testified that there were several remaining parameters before Merck and Weider could reach an agreement regarding a sale, including patent infringement and legal issues, as well as approval from Merck & Cie (known as Eprova at the time). TT114:18-115:4, 119:17-21. Dr. Martin testified that Weider would be aware of these additional requirements because they were known practices in this industry. TT140:5-19. And Dr. Buchholz confirmed that these were industry standard requirements for an agreement. TT729:16-730:4. Such industry practices are relevant to the § 102(b) analysis of whether there has been an offer for sale. *Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1348 (Fed. Cir. 2003). Watson has no rebuttal to this evidence from Drs. Buchholz, Bucci, and Martin. It is Watson's burden, and Watson's failure to respond to this testimony dooms its invalidity case.

The documents also reflect those same considerations and remaining hurdles to the supposed sale of 2kg of Metafolin® in the fall of 1998. DTX83 at 2 (10/8/98 Memo from Buchholz to George Lengvari at Weider summarizing contributions of Merck, including toxicology); TT735:12-736:8 (Buchholz). The documents also demonstrate that the parties had numerous and changing ideas for what product Weider would even propose to launch. DTX46 (9/14/98 Bucci suggestions); DTX134 (12/16/98 list of options for product from 12/14-15/98 Germany meeting). The evidence is unrebutted that issues like toxicology, patent infringement, liability apportionment, and regulatory matters remained to be resolved before either party could commit or be legally bound to a contract for sale of 62 million doses of the putative product. TT738:15-24; DTX46.

Watson fails to address this and other contemporaneous evidence of Merck's and Weider's understanding about whether there was a binding offer or a contract; evidence Plaintiffs carefully walked through and cited in closing. TT845-860. One of the most significant documents is the Gary Jepson/Preston Zoller e-mail chain (PTX94, below) that provides evidence of what Weider

and Merck believed about the proposed transaction for 2kg of Metafolin®.[2] In this e-mail Gary Jepson, the same Gary Jepson who corresponded with Dr. Martin in September 1998,[3] wrote that Weider's communications amounted to "an indicat[ion] of interest for 2Kg" and Preston Zoller reported that Merck did not expect Weider to "buy any immediately." It is hard to imagine a characterization further from Watson's theory of a binding offer and consummated contract than this contemporaneous evidence.

From: Preston Zoller
To: James Hine, Luke Bucci
Date: Wed, Jan 6, 1999 11:47 AM
Subject: Re: Fwd: 5-MTHF

Jim/Luke-- Sounds like we have to fish or cut bait.
Yesterday our discussion with Eric W. and Rick left the impression that 5-mthf was not on a fast track to anywhere.
Similarly, in Darmstadt, Lutz Thomas indicated that Merck wasn't expecting us to buy any immediately.
It's my understanding that there wouldn't be any dire consequences to cancelling the P.O.,(if one exists) until such time as a new 5-MTHF product is actually approved for launch. And the likelihood of that seems less than 50-50 at the moment.
Comments? Preston

>>> Gary Jepson 01/06 10:18 AM >>>
EMerck is calling asking about whether the PO for 5-MTHF is active. The price was $25,000/kg and we had indicated an interest for 2Kg.

If we purchase this material, it will have to be charged to a research budget since it does not fall under the guidelines for an inventoriable asset. Please advise department number and account number to charge.

If we do not want this material, please let me know so that I can clarify the order status with EMerck.

I have attached Rob's last memo on the subject.

Best regards

Merck had no expectation that Weider would buy any 5-mthf—*i.e.* no contract was in place

Weider believed there were no "dire consequences to cancelling the P.O., (if one exists)"– consistent with Weider having no legal obligations

Weider believed that actual approval was required before there could be a launch and that was unlikely

Weider's purchase order was just an "indicat[ion] of interest for 2Kg"

Note also Weider's informality and uncertainty about whether a purchase order even existed. Watson cannot prove a legally binding commercial sale by clear and convincing evidence when there is a substantial question over whether Weider even sent the purchase order. Weider's informality

[2] Watson's sole response on PTX94 is to criticize Plaintiffs for not offering testimony about it. Def. Br. 16 n.8. This is not a substantive response to the document, which requires no testimony to explain. Moreover, Watson cannot criticize Plaintiffs for not collecting redundant supporting evidence during fact discovery when Watson failed to disclose its theories regarding § 5.2 until post-trial briefing. Instead of addressing evidence showing what Weider employees said about whether there was anything legally binding here (PTX94), Watson devotes significant time to its AHP theory that Merck was leading Weider along. Def. Br. 4-5. This theory is unsupported by any evidence and gets who-led-whom-along backwards. It was Weider going to Germany on diplomacy meetings in December 1998 just 11 business days before deciding to end the project. *Compare* DTX134 (saying Weider will try and launch a product) *with* PTX94 (Weider decision days later to kill project).

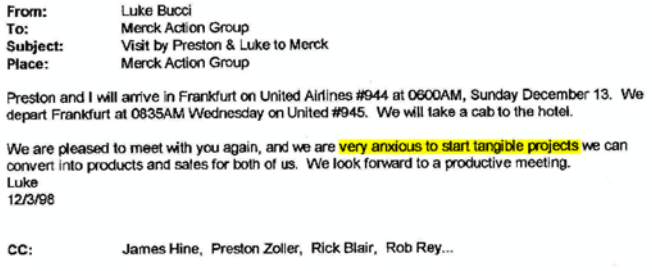
[3] Evidence of the parties' subsequent conduct can be used to determine whether a binding contract exists. *Cargill, Inc. v. Biodiesel of Las Vegas, Inc.*, No. 2:09-CV-02134-JCM, 2010 WL 4121850, at *3 (D. Nev. Sept. 8, 2010); *cf.* U.C.C. § 2-207(3) (subsequent conduct can recognize existence of contract).

also underscores Dr. Bucci's testimony—that without a formal contract "it was all discussions"—from the Martin faxes to the potentially phantom purchase order. TT213:3-9.

The same view that the discussions were preliminary in nature and non-binding held for Merck. Dr. Buchholz had overall supervision of the entire Weider relationship. He testified that there could be no legal obligations until there was a formal contract, which would include ordinary contracts for single transfers of material. TT714:19-24, 728:4-23, 730:5-18. As for Dr. Martin, Watson wants to myopically focus on his faxes but not on his testimony, wherein he explained to Watson's counsel that no sale could be confirmed until all the parameters were met.

> Q: Okay.
>
> A: But this doesn't mean automatically they get the confirmation.
>
> Q: But it says here, you will get the official confirmation, right?
>
> A: This means always after the check, and if everything is in order, they will get a confirmation.
>
> Q: Okay.
>
> A: Maybe as, I don't know from, from the English what -- you will get, this means you get it if, of course, everything is in order with all these, these checks in between.
>
> Q: Okay.
>
> A: This is my, my, from -- I'm a German, yeah, and...
>
> Q: In this communication, you do not tell Weider that their order is subject to an official confirmation, correct; you say that they will get the official confirmation?
>
> A: Again, from, from my German-English, yeah, when we receive an order, after all the checks, they will get an official confirmation if everything in order; otherwise, we cannot deliver, yeah, if we have not all the parameters checked.

TT125:12-126:4, 126:7-17 (discussing DTX133). Weider understood Dr. Martin perfectly, which is why, with few of these parameters yet met, Weider said they were looking forward to "start[ing]



From: Luke Bucci
To: Merck Action Group
Subject: Visit by Preston & Luke to Merck
Place: Merck Action Group

Preston and I will arrive in Frankfurt on United Airlines #944 at 0600AM, Sunday December 13. We depart Frankfurt at 0835AM Wednesday on United #945. We will take a cab to the hotel.

We are pleased to meet with you again, and we are very anxious to start tangible projects we can convert into products and sales for both of us. We look forward to a productive meeting.
Luke
12/3/98

CC: James Hine, Preston Zoller, Rick Blair, Rob Rey...

tangible projects" in *December 1998*, in another document Watson fails to address. DTX52 (above, highlighting added).

Watson's only factual rebuttal is a single statement from Dr. Bucci, in which he said that he expected delivery of the 2kg. Dr. Bucci did not testify that he expected delivery because Merck was legally obligated to deliver it. His expectation of delivery at some point in time is consistent with his belief that no binding contract had been formed yet and that continuing meetings and negotiations would lead to "tangible projects." Dr. Bucci expected delivery because he expected Weider to identify a product in which to place 62 million doses, and he expected Merck and Weider to address all the outstanding parameters necessary for a sale, like toxicological data. Watson has failed to present any evidence that Dr. Bucci's business expectation amounted to a belief that Merck and Weider had entered into a legally binding agreement to deliver 2kg of product.

With its heavy burden and the totality of the evidence against it, Watson chooses to ignore key documents (such as PTX94) that undercut its implausible narrative of a legally binding contract. Watson also chooses its post-trial brief to launch brand new legal theories regarding § 5.2. But Watson's new arguments regarding § 5.2 are as wrong as its selective reading of the evidence.

B. Watson's Case Incorrectly Assumes A Legally Binding Offer Exists Based On Cherry-Picked Evidence And Then Forces All The Remaining Evidence To Fit This Assumption

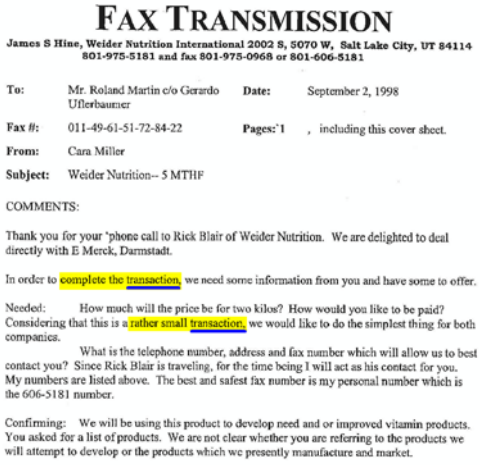
Watson's entire trial presentation, from opening to closing to its post-trial brief, follows the same script. Watson first presents its cherry-picked selection of the evidence, including the Martin faxes and the e-mails regarding a purchase order. During this time Watson does not address § 5.2. *See, e.g.*, Def. Br. 2-11 (failing to address the substance of § 5.2). Watson takes the evidence in this order despite the fact that the CDA and its § 5.2 predate all of the communications on which Watson relies. Based on this incomplete and one-sided review of a minority of the evidence, Watson then forces every other fact in the case to bend to its pre-existing narrative. Thus, for

Watson, it does not matter what Drs. Martin, Bucci, and Buchholz testified regarding the preliminary nature of the discussions regarding the 2kg transaction, and it must not matter what Weider itself said about the 2kg transaction in PTX94. The denouement of this strategy is Watson's argument that because what Martin did "established" a legally binding offer, it must be true that § 5.2 of the CDA does not affect that conclusion. Watson's case puts the cart before the horse. Its arguments that the 2kg, 62MM dose supply was not a "transaction" and its new idea that Merck, without saying a word, waived the protections of § 5.2, get the logic precisely backwards. Section 5.2 sets the rules of the road; Watson cannot treat it as a bump in the road.

1. The evidence supports interpreting "transaction" in § 5.2 to include the 2kg order

Watson's primary argument is that § 5.2 does not apply because the word "transaction" does not cover the discussions regarding 2kg of Metafolin®. Def. Br. 13-14. Watson tells the Court to refer to the extrinsic evidence to find the term "transaction" ambiguous. Def. Br. 14-15.[4] First, Plaintiffs disagree that "transaction" can be ambiguous as it is a well-understood contractual term that would cover the 2kg discussions. *See, e.g.*, *Transaction*, Black's Law Dictionary (6th ed. 1990) (defining "transaction" as "[a]n act, agreement, or several acts or agreements between or among parties whereby a cause of action or alteration of legal rights occur").

[4] While Utah law would govern a dispute between Merck and Weider on the CDA, *Group One* holds that general federal law should control a § 102(b) analysis. 254 F.3d at 1048. Regardless of which law the Court consults, Watson oversimplifies it. Utah law does appear to allow consideration of extrinsic evidence, but requires the resulting interpretations to be reasonably supported by the language of the contract. *See Selvig v. Blockbuster Enterprises, LC*, 266 P.3d 691, 697 (Utah 2011); *but see Glenn v. Reese*, 225 P.3d 185, 189 (Utah 2009) ("The court considers extrinsic evidence of the parties' intent only if the language of the contract is ambiguous."). There is considerable debate on whether extrinsic evidence should be considered in deciding whether a contract is ambiguous, as the hundreds of cases collected here show. 40 A.L.R.3d 1384. The traditional rule is that only the written contract can be examined to first determine ambiguity. *Id.* § II.3. However, whether the Court considers the plain language of § 5.2 with or without the extrinsic evidence, the result is the same. "Transaction" includes a possible 2kg transfer of 62 million doses of Metafolin®.



FAX TRANSMISSION

James S Hine, Weider Nutrition International 2002 S, 5070 W, Salt Lake City, UT 84114
801-975-5181 and fax 801-975-0968 or 801-606-5181

To: Mr. Roland Martin c/o Gerardo Uflerbaumer **Date:** September 2, 1998

Fax #: 011-49-61-51-72-84-22 **Pages:** 1 , including this cover sheet.

From: Cara Miller

Subject: Weider Nutrition-- 5 MTHF

COMMENTS:

Thank you for your 'phone call to Rick Blair of Weider Nutrition. We are delighted to deal directly with E Merck, Darmstadt.

In order to complete the transaction, we need some information from you and have some to offer.

Needed: How much will the price be for two kilos? How would you like to be paid? Considering that this is a rather small transaction, we would like to do the simplest thing for both companies.

What is the telephone number, address and fax number which will allow us to best contact you? Since Rick Blair is traveling, for the time being I will act as his contact for you. My numbers are listed above. The best and safest fax number is my personal number which is the 606-5181 number.

Confirming: We will be using this product to develop need and or improved vitamin products. You asked for a list of products. We are not clear whether you are referring to the products we will attempt to develop or the products which we presently manufacture and market.

But even so, Watson provides no extrinsic evidence, just argument about what "transaction" "may be properly construed to mean" along with its re-tread that the Martin faxes were legally binding offers. Def. Br. 14-15. There is, however, actual extrinsic evidence of whether Merck and Weider considered the 2kg order a transaction. The Court may remember DTX79 (left, highlighting and underlining added), the September 2, 1998 fax from James Hine of Weider to Roland Martin—Plaintiffs referred to it in opening to explain why this "transaction" argument was dead on arrival. TT59:10-20. Mr. Hine twice refers to the "transaction" for 2kg and never once suggests it is not covered by the provisions of the CDA.

Watson's argument also ignores its concession at closing that the CDA was in effect during the time of the Martin faxes. TT794:9-15. The Martin faxes attached all sorts of Merck confidential information, including product specifications and batch data. DTX27 at 3-5. Watson cannot and does not dispute that Merck and Weider intended this information to remain confidential pursuant to the CDA. But § 3 of the CDA restricts the use of any confidential information to "evaluating a possible transaction with the Disclosing Party." DTX65 at 3. If the 2kg order is not a "transaction" for purposes of the CDA then there was no lawful use Weider could have made of the information Dr. Martin provided. The extrinsic evidence is consistent with Watson's concession that the CDA governed the information disclosure and contradicts its argument on the meaning of "transaction."

2. Watson's construction of "definitive agreement" ignores words of § 5.2 that immediately follow that term and the extrinsic evidence Watson says the Court should consult

Watson attempts to remove the requirement that any transaction be memorialized by a "definitive agreement" by arguing that the Martin communications could be that definitive

agreement. Def. Br. 13. Aside from the facially implausible nature of that argument, Watson's problem is that § 5.2 does not just say "definitive agreement," it says "definitive agreement … *signed by both parties*." DTX65 at 4 (emphasis added). While Watson has tried to insinuate that certain emails satisfy this requirement (*see supra* § I.A.2) Watson has never identified any document "signed by both parties" that could colorably be the required "definitive agreement."

Just like with "transaction," Watson also ignores the unrebutted and unchallenged extrinsic evidence from Dr. Buchholz, who signed the CDA for Merck, as well as third-party Dr. Bucci. Both testified that § 5.2 required a "formal agreement and contract," i.e., a "signed agreement," that never materialized. TT208:7-16, 213:3-9 (Bucci), 728:4-14 (Buchholz). After appealing to the extrinsic evidence, Watson does not even address what the signatory to this contract and his primary counterpart at Weider had to say about its meaning.

Merck and Weider specifically contracted for § 5.2's protections in order to allow them to have free and open continuing discussions without fear of incurring legal obligations to one another; "major negative consequences" as Dr. Buchholz put it, or "dire consequences" as Preston Zoller of Weider put it. TT726:18-728:14 (Buchholz); PTX94 (Zoller). But according to Watson, § 5.2 is legally nugatory, because as soon as Roland Martin did something that even arguably could be a legally binding offer in the absence of § 5.2, that worked a waiver of § 5.2's protections. Section 5.2 cannot be read out of the case by this circular logic.

3. Watson cannot read § 5.2 out of the case with its brand new "waiver" argument that renders § 5.2 meaningless

In a hypothetical universe without § 5.2, the question for the Court would be whether the Martin faxes were legally binding offers capable of simple acceptance. In this real case where § 5.2 and the CDA govern Weider and Merck's discussions, Watson refuses to modify the question. Instead, according to Watson's theory, Merck's actions that, in the absence § 5.2, could have been potentially deemed a legally binding offer, result in Merck waiving its rights under § 5.2. This waiver

argument finds no basis in the evidence and Watson's cases are easily distinguishable from this one. Finally, Watson's waiver argument should be precluded under Federal Rule of Civil Procedure 37(c) because it is raised for the first time in its post-trial brief and has never been disclosed before, in violation of Rule 26(e).

Watson's argument that Merck waived its rights under § 5.2 is circular—that § 5.2 does not render Merck's actions non-binding because the very circumstances invoking § 5.2's protection operate to waive it. The only evidence of waiver Watson points to are the Martin faxes themselves. Def. Br. 16. Thus, according to Watson, Martin had to write at the bottom of every fax "this is not a legally binding offer" because failure to do so resulted in waiver of § 5.2's protections. But § 5.2 sets the default rule such that such explicit disclaimers are unnecessary. Under Watson's view, § 5.2 actually accomplishes nothing because failure to specifically say a communication is non-binding is *per se* waiver of the CDA's command that such communications are assumed non-binding. No case holds that and the cases Watson cites are inapposite.

Those cases show what real waiver looks like.[5] In *Lone Mountain Production Co. v. Natural Gas Pipeline Co. of America*, 984 F.2d 1551 (10th Cir. 1992), Defendant Natural Gas waited nearly two years to assert its technical rights that the court deemed waived. *Id.* at 1556-57. The court relied on Utah law that "a party to a contract 'should not be permitted to deliberately mislead the offeree into believing that he doesn't have to comply strictly with its requirements; then when the latter has relied upon such representation and gotten into a position where it is practically impossible to perform, suddenly reverse position and demand compliance, for the purpose of getting out of the transaction.'" *Id.* (quoting *Caldwell v. Anschutz Drilling Co.*, 13 Utah 2d 177, 179, 369 P.2d 964, 966 (1962)). Nothing of the sort is present in this case. There was no long period of silence and Dr.

[5] Watson does not identify whether, per *Group One*, federal law applies to the waiver issue or some other jurisdiction (e.g., Utah). As with the use of extrinsic evidence, the Court need not determine this issue because the result is the same regardless. *See supra* n.4.

Martin did not "deliberately mislead" Weider and then "reverse position." So too are Watson's other cases finding waiver distinguishable from this case. *See Evco Leasing Corp. v. Ace Trucking Co.*, 828 F.2d 188, 196 (3d Cir. 1987) (finding forbearance to object for twenty months and requests for postponements to constitute waiver); *Innospec Fuel Specialties, LLC v. Isochem N. Am., LLC*, No. CIV. 10-1642, 2012 WL 3682988, at *5 (D.N.J. Aug. 24, 2012) (finding four years of non-assertion of rights and acceptance of payments to constitute waiver).

Watson also makes no effort to address the requirement that it show an intent to waive—a requirement identified in the authorities cited in Watson's brief. *See In re Krueger*, 192 F.3d 733, 739 (7th Cir. 1999) (finding no waiver because no evidence of intent). "A waiver is the intentional relinquishment of a known right. To constitute waiver, there must be an existing right, benefit or advantage, a knowledge of its existence, and an intention to relinquish it. We further clarify that the intent to relinquish a right must be distinct." *Soter's, Inc. v. Deseret Fed. Sav. & Loan Ass'n*, 857 P.2d 935, 942 (Utah 1993) (citations and internal quotation marks omitted). There is no testimony or document supporting the idea that Merck intended to waive its rights under § 5.2, and therefore Watson's burden presents an insuperable barrier to this late and unsupported waiver argument.

Finally, Watson's waiver argument should be excluded because Watson never raised prior to its post-trial brief—not in its discovery responses, not in its invalidity contentions, nor in its putative summary judgment brief. *See* Ex. A, Watson's Objs. & Third Supp. Resps. to First Set of Interrogs. at 34-43, 64-81 (Oct. 31, 2014); Ex. B, Watson's Supp. Invalid. Content. at 23-32 (Sept. 30, 2014); D.I. 76.2. Watson's failure to raise the argument violates the requirements of Federal Rule of Civil Procedure 26(e), and the result is preclusion of under Rule 37(c), "unless the failure was substantially justified or is harmless." *See Nicholas v. Penn. State Univ.*, 227 F.3d 133, 148 (3d Cir. 2000). The Court could easily conclude that Plaintiffs are not prejudiced, but only because this new argument is

baseless and wrong. Indulging this waiver argument at all, however, would be *per se* prejudicial—because this is not just the trial-by-ambush Rule 37 seeks to prevent, but a *post-trial*-by-ambush.

Watson's § 102(b) challenge is built on a backwards view of the evidence where every inconsistent document, all contrary testimony, and even the law has to be viewed through Watson's skewed lens of a small portion of the evidence: the Martin faxes. Similarly, Watson's technical case ignores the legal requirements of inherent anticipation—e.g., its failure to perform the experiment of the '850 Patent while maintaining that it inherently anticipates the Type I crystal—and ignores contrary evidence, as with its failure to acknowledge Dr. Marsden's testimony.

II. CLAIM 4 IS NOT ANTICIPATED BY THE '850 PATENT

Watson presented two inherent anticipation theories at trial. The first is that the product of the '850 Patent Example 3 must have been, by a series of deductions and a process of elimination, the Type I crystal form of Claim 4. Def. Br. 20, 23. Watson's expert, Dr. Robin Rogers, admitted nearly a dozen times that his opinion was based on his belief that the experiments in the '850 Patent actually occurred. But they did not. The experiments of the '850 Patent are paper, or prophetic, examples under the patent law. They did not happen. Moreover, the product described in the '850 Patent is not "necessarily" the Type I crystal, because every single one of Watson's deductions is either wrong on its face or subject to significant uncertainty—in particular the assumption that the '850 Patent's "practically insoluble" final product is the same as the "sparingly soluble" Type I crystal. Watson tried to argue a scientific impossibility by equating these two when the very source on which its expert relied shows that they are one hundred times different.

Watson's second argument is that if a person of skill in the art performs Example 3 of the '850 Patent, it will necessarily produce the Type I crystal. Def. Br. 25. Watson retreated from and deemphasized this argument in its post-trial brief because the evidence showed it is wrong. Watson never even tried to do any of the steps of the '850 Patent. Plaintiffs' expert Dr. Allan Myerson did,

and proved that the '850 Patent not only fails to "necessarily" produce the Type I crystal, but does not even enable what it purports to describe, and therefore cannot be an anticipatory reference under Federal Circuit case law. Finally, the irrelevant experiment Watson did perform was contaminated with a seed of the very Type I crystal Watson was trying to produce—as Watson's own expert Dr. Marsden admitted before Watson started frantically questioning his qualifications.

The '850 Patent does not disclose the 2-theta values that Claim 4 of the '168 Patent uses to uniquely identify the Type I crystal form, so Watson must find them inherently. But neither of Watson's inherent anticipation arguments comes anywhere close to meeting the Federal Circuit's exacting test that the "missing descriptive material is necessarily present, not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed Cir. 2002) (internal quotation marks omitted); *In re Armodafinil Patent Litig. Inc.*, 939 F. Supp. 2d 456, 465 (D. Del. 2013) (stating that an "undisclosed feature must 'necessarily and inevitably' flow" from prior art, and "if the teachings of the prior art can be practiced in a way that yields a product lacking the allegedly inherent property, the prior art in question does not inherently anticipate").

A. The Product Of The '850 Patent Example 3 Exists Only On Paper, But Dr. Rogers Based His Opinion On What He Called "Real Data"

There are two types of examples in U.S. patent law. "Working examples correspond to work actually performed and may describe tests which have actually been conducted and results that were achieved." MPEP § 608.01(p)(II). The other type of example is called a "paper" or "prophetic" example. "Simulated or predicted test results and prophetical examples (paper examples) are permitted in patent applications." *Id.* These "describe the manner of process of making an embodiment of the invention *which has not actually been conducted*." *Id.* (emphasis added). While they are allowed, the MPEP concludes with the injunction that "[p]aper examples should not be represented as work actually done …. [and] should not be described using the past tense." *Id.* Thus, prophetic, or paper, examples are written in the present tense. *Schering Corp. v. Geneva Pharm., Inc.*,

339 F.3d 1373, 1376 n.1 (Fed. Cir. 2003) ("Prophetic examples are set forth in the present tense to indicate that they were not carried out.").

Dr. Rogers either did not know this or chose to ignore it when he reviewed and gave opinions on the '850 Patent. Every single example in the '850 Patent is a paper example written in the present tense "to indicate that they were not carried out." DTX332 *passim*; TT403:5-9. But, Dr. Rogers emphasized repeatedly that his opinion on inherent anticipation depended on his view that the '850 Patent reported actual experimental results. *See, e.g.*, TT398:23-399:13 (agreeing basis for opinion "is the '850 inventors were able to and, in fact, did produce" the Type I crystal), 299:3-7 ("'850, on the other hand, shows me they *did* the fractional crystallization, because they *got* the compound. They *got* it pure. They *got* it crystalline and they *were able to characterize it with real data*." (emphases added)), 399:14-400:4 ("I was taking that they reported the data that they got, yes."), 498:7-13 ("It's talking about a product that it obtained and giving real data."), 290:2-11 ("they've made that in situ"), 292:10-293:19 ("it actually gives the data that was collected"), 293:20-294:8 ("they had a crystalline pentahydrate practically insoluble in water"), 299:13-18 ("[t]hey obtained a crystalline material").

The '850 Patent inventors did not "get it pure" or "get it crystalline." They got nothing at all. There is no dispute that the '850 Patent has paper examples that "were not carried out" because they are written in the present tense. The central premise of Dr. Rogers' opinion is wrong. While Plaintiffs pointed this out in closing, Watson elected not to address the issue in its post-trial brief.

There is no evidence that a physical product from the '850 Patent ever existed and to conclude otherwise would be to conclude the '850 Patent was written in violation of the MPEP. Without "real data," Watson should have tried to perform meaningful experiments—i.e., one replicating the steps of the '850 patent—but it chose not to. *See infra* §§ II.D & F. But even if the '850 Patent Example 3 contained "real data," each of Watson's deductions and eliminations fails the

Federal Circuit's inherency test of "necessarily," not "probably or possibly." And on solubility, the "real data" of the '850 Patent is one hundred times different than the actual, real, data on Type I.

B. Even If It Were Real, The '850 Patent Product Is 100x Less Soluble Than The Type I Crystal; And Therefore Is *Not* The Type I Crystal

A compound's solubility can be measured quantitatively (as a certain mass of solid dissolved in a certain amount of a solvent, like water, or as a percentage) or described qualitatively (e.g., "soluble," "sparingly soluble," "slightly soluble," "practically insoluble"). As Dr. Rogers acknowledged, qualitative descriptions of solubility like *sparingly soluble* and *practically insoluble* are defined terms of art understood as such by persons of ordinary skill. TT421:23-422:2. For example, the United States Pharmacopeia ("USP"), a respected standards-setting reference upon which Dr. Rogers himself relied (TT422:8-12), includes the definitions for these terms. PTX195 at 6 (above, highlighting added); *see also* PTX196 at 6 (showing the FDA adopts these definitions). The term "practically insoluble" is defined as greater than 10,000 parts of solvent required to dissolve 1 part of solid (or less than 0.01% solubility). *Id.*; TT423:19-424:12. In comparison, a "sparingly soluble" compound is at least 100 times more soluble. A sparingly soluble compound requires only 30 to 100 parts of solvent to dissolve one part solid (or about 1% solubility at the low end). PTX195 at 6; TT425:7-15. Dr. Rogers conceded all of this when confronted with the definitions of these terms, after having left these definitions out on direct and having equated these two terms that are orders of magnitude different. TT299:19-302:8.

The approximate solubility of a compendial substance is indicated by one of the following descriptive terms:

Descriptive Term	Parts of Solvent Required for 1 Part of Solute
Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1,000
Very slightly soluble	From 1,000 to 10,000
Practically insoluble, or Insoluble	Greater than or equal to 10,000

The '850 Patent product is described as "practically insoluble in water." DTX332 at 4:9-10; TT421:20-22. The '850 Patent product cannot be the Type I crystal because the Type I crystal is not *practically insoluble*, it is *sparingly soluble* in water—greater than 100 times more soluble than the '850 Patent product. In its Drug Master File documentation to the FDA, Merck described the Type I

crystal as "sparingly soluble." The water solubility data provided in the '168 Patent on the Type I crystal—1.1%—meets the accepted definition of sparingly soluble from the USP, which Dr. Rogers conceded a person of ordinary skill would recognize. DTX2 at 4:49-60 (right); TT431:19-432:8.

Example 3

Solubilities

The solubility of the crystalline calcium salt of 5-methyl-(6S)-tetrahydrofolic acid is given in the following Table:

	Solubility at 20° C. in	
Type	0.9% NaCl	water
Type I	1.6%	1.1%
Type II	5.8%	3.8%
Type III	1.5%	1.0%

As a result, Watson's inherent anticipation argument fails not only because the '850 Patent does not describe a real product with real data, but also because the data it does provide on solubility proves the "product" cannot be a Type I crystal. The practically insoluble (<0.01%) '850 Patent product does not match the sparingly soluble (1.1%) Type I crystal. Despite Plaintiffs having highlighted this flaw in Watson's "simple process of elimination" in both cross-examination of Dr. Rogers and in closing, Watson does not address it. Watson instead relies on other deductions regarding the '850 Patent product that do not help meet its burden because those deductions amount to nothing more than a collection of maybes and possibilities, and not the necessities that the law of inherency requires.

C. Even If The '850 Patent Product Were Real, Watson's Remaining Deductions Are "Maybes" And "Possibilities" And Therefore Do Not Support An Inherent Anticipation Challenge

Watson's efforts to restrict the supposed product of the '850 Patent to the Type I crystal rely on additional deductions as part of its "simple process of elimination." Watson has to prove each of these deductions as necessarily true to eliminate all other possible candidates for the '850 Patent product. Because if it is even just *possible* that some other polymorph of calcium 5-methyl-(6S)-tetrahydrofolate could be the product in the '850 Patent, Watson cannot prove the '850 Patent necessarily and inevitably produces the claimed invention.

Watson's argument fails in the face of the evidence. For example, Watson has to prove that there are *necessarily* no undiscovered polymorphs of calcium 5-methyl-(6S)-tetrahydrofolate. As Dr.

Myerson testified, new polymorphs of existing compounds are often found years later—e.g., aspirin, Ritonavir, etc. TT641:21-642:23. The company Merck hired to look for new polymorphs recommended additional testing that "may reveal other unknown modifications with varying water contents" and that "could open up another possibility to obtain new polymorphic forms." DTX302 at 426, 461. Dr. Rogers conceded that he provided no evidence or opinion that this additional recommended testing has ever been done, instead discounting these portions of the Solvias reports that contradict his opinions as "trying to drum up business." TT416:1-7, 420:24-421:6.

Watson also adds unsupported inferences to the evidence in order to make its case. Watson's theory requires that the '850 Patent product be a pentahydrate, which Watson says the '850 describes with a "measured water content of 15.27%." Def. Br. 20 (internal quotation marks omitted). But the '850 Patent does not say the product has a "measured water content," it describes a "moisture." The '850 Patent is notably silent on how it determined this "moisture" (not surprising in a prophetic example) and does not describe any kind of drying steps prior to determining this "moisture." In the absence of evidence of drying, or that "moisture" is the same as "water of crystallization," Watson merely assumes the truth of its own conclusion—drying is standard therefore it must have happened.[6] When persons of skill dry a reaction product and measure water content, however, they record it. The '168 Patent does this (DTX2 at 5:8, 42, 63, 6:13, 33, 50, 63), as does the Merck batch record for a Type I crystal with low water content (PTX139 at 362395).[7]

Even if one ignores the absence of a drying step and assumes "moisture" means "water of

[6] Watson's appeal to the Examiner's conclusion that the '850 Patent disclosed a pentahydrate (Def. Br. 22) is in contrast to its position that the Examiner mistakenly allowed Claim 4 (Def. Br. 31) because he was unable to recognize that the Type I form could be a pentahydrate—a fact disclosed in the Examples of the '168 Patent. DTX2 at 5:67 (Type I water content of 14.5%).

[7] Watson is incorrect in its brief when it claims "similar silence" on drying in the Merck batch record. Def. Br. 23. The batch record clearly describes a drying step before a measurement of water content, the low result of which caused the additional XRPD analysis to prove that the crystal containing 6-8% water was still the Type I crystal, as Dr. Myerson testified unrebutted. PTX139 at 362395-96 (translation follows original); TT665:18-666:15.

crystallization," Watson still has to contort the plain language of the '168 Patent in order to limit pentahydrate forms of calcium 5-methyl-(6S)-tetrahydrofolate to just Type I. The Court will recall that the '168 Patent unambiguously says that calcium 5-methyl-(6S)-tetrahydrofolate's crystal salts have "at least 1 equivalent of water" of crystallization, and the different forms identified "typically contain" water of crystallization in different ranges, including Type III and IV which typically contain 5 or fewer waters. DTX2 at 2:12-19. First, Watson has to rewrite the water content of Types III and IV because the plain language of the '168 Patent allows both of those forms to be pentahydrates. For this there is no actual evidence, just Dr. Rogers' non-expert weighing of the different language in the earlier Swiss application versus the later U.S. application. Second, Watson redefines the word "typically" to mean "always" in order to limit pentahydrate forms of calcium 5-methyl-(6S)-tetrahydrofolate to only the Type I crystal. Dr. Rogers agreed that "typically" does not mean "always." TT487:6-8. That means that Type I crystals are not the only possible forms of calcium 5-methyl-(6S)-tetrahydrofolate that could exist as pentahydrates.

Added up, Watson's purported evidence that the '850 Patent Example 3 produces a Type I crystal does not even rise to the level of "probable," let alone the required level of proving it "necessarily" results in the Type I crystal. Watson's process of elimination relies on this unrealistic set of "possibilities" or is just scientifically 100-times wrong, as in the case of "practically insoluble." Watson had the opportunity to perform actual experiments replicating the procedure from the prophetic Example 3 to try to show that the Type I crystal necessarily resulted from following the '850 Patent's teachings. Watson did not do this. It chose not to follow a single step of the '850 Patent Example 3 experimental procedure, and as a result, Watson cannot prove anticipation.

D. Watson's Boiling Water Procedure Cannot Show Inherent Anticipation Because Watson Did Not Follow The '850 Patent

Watson's inherent anticipation argument thus boils down to a single experimental procedure. This procedure's results do not inherently anticipate Claim 4 because the procedure did not follow

the '850 Patent. In order for prior art to inherently anticipate, the claimed invention must "invariably happen" when the procedure is "faithfully followed." *Valeant Int'l (Barbados) SRL v. Watson Pharm., Inc.*, No. 10-20526-CIV, 2011 WL 6792653, at *5 (S.D. Fla. Nov. 8, 2011) (internal quotation marks omitted). Dr. Rogers said that a person of ordinary skill could follow the '850 Patent procedure (TT294:11-295:5), and Dr. Marsden was confident that he could have done so if Watson asked. TT550:2-9. But Watson's experts did not faithfully perform a single step of the '850 Patent procedure.[8] TT405:7-407:23, 410:3-12 (Rogers); TT549:20-550:1 (Marsden). Watson's choice defeats inherent anticipation.

Instead of following the '850 Patent procedure, Watson followed a different procedure that is not prior art—Watson's own proprietary process for manufacturing calcium 5-methyl-(6S)-tetrahydrofolate first published in 2013. TT511:16-512:9, 537:2-7, 548:22-549:8 (Marsden); PTX164; PTX166. Whatever product emerges from Watson's own internal procedure, it is not evidence of what would "necessarily" result from following the procedure of the '850 Patent. Watson even conceded to the Court at closing that "[w]e don't, we don't actually know" whether "what [] he made is the same thing as what the '850 Patent says he made." TT808:2-10.

Watson's single recrystallization on a product synthesized according to a non-prior art procedure cannot prove inherent anticipation by the '850 Patent. Especially when balanced against Plaintiffs' experimental evidence that following the actual '850 procedure not only fails to necessarily and inevitably produce the Type I crystal, but is inoperable and therefore not enabled.

E. Plaintiffs Attempted The '850 Patent Procedure And Proved It Is Not Enabled And Cannot Anticipate Claim 4

Unlike Watson, Plaintiffs attempted to replicate the procedure of the '850 Patent.

[8] The only procedure Watson purported to perform was a recrystallization from boiling water—a procedure styled after the final step in the '850 Patent procedure ("[i]t can be recrystallized from boiling water"). DTX332 at 4:5-6. But even this effort falls short because, as Dr. Rogers admitted, he did not even have the same starting "it" as the '850 Patent for use in his attempted recrystallization. TT410:9-12.

TT644:11-14, 645:23-646:3 (Myerson). Dr. Myerson's experiments proved that actually following the '850 Patent's prophetic procedure does not produce the Type I crystal and is, in fact, nonfunctional. First, step 9 of the procedure (DTX332 at 3:27-31) resulted in a "paste" when it was supposed to create a liquid mixture to filter. TT646:8-23. Second, the '850 procedure created a racemic crystal, not the pure 6S crystal form. TT645:7-22. Thus, the only experimental evidence in this case is that the '850 Patent procedure does not "necessarily" make the Type I crystal and does not, therefore, inherently anticipate Claim 4.

Because the '850 Patent's paper examples are inoperable, it is not enabled and cannot anticipate Claim 4 under any theory. In order for a prior art patent to be anticipatory, it must be enabled. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003). Though an anticipatory prior art patent is presumed enabled, that presumption is overcome "[i]f a patentee presents evidence of nonenablement that a trial court finds persuasive." *Id.* at 1355. A patent that is inoperable cannot be enabled. *Bone Care Int'l, LLC v. Pentech Pharm., Inc.*, 862 F. Supp. 2d 790, 814 (N.D. Ill. 2012); *Ex Parte Kumar*, APL 2009-002499, 2009 WL 3490272, at *4-5 (B.P.A.I. July 21, 2009) (finding prior art not enabled and not anticipatory based on expert testimony that method disclosed did not work). Dr. Myerson's attempted replication demonstrates nonenablement.

Watson must now "ultimately demonstrate by clear and convincing evidence that the prior art is enabled." *Robocast, Inc. v. Apple Inc.*, 39 F. Supp. 3d 552, 565-66 (D. Del. 2014). Watson has failed to meet that burden, resting its defense of the '850 Patent just on the underlying presumption. Def. Br. 24. The evidence Watson claims supports its argument that the presumption remains intact is Dr. Myerson's alleged procedural "deviation," which Watson claims invalidates his experiment. Dr. Myerson's "deviation" was an adjustment undertaken in light of the nonenabled, inoperable nature of the paper procedure—the addition of water to break up the unfilterable "paste." TT646:8-

23. Dr. Myerson's purported "deviation" is part of the evidence that the '850 Patent is not enabled; not evidence that the paper example works.

Because it is not enabled, the '850 Patent should be excluded as an anticipatory reference. *Amgen*, 314 F.3d at 1355 ("If a patentee presents evidence of nonenablement that a trial court finds persuasive, the trial court must then exclude that particular prior art patent in any anticipation inquiry …."). The '850 Patent itself, and the Watson experiment purporting to "confirm" it, both fail to prove inherent anticipation of Claim 4.

Even if the Court were inclined to consider the '850 Patent and Watson's boiling water procedure allegedly supporting it, the results of Watson's procedure are unreliable and invalid because Dr. Rogers' starting material—his Material 1—was seeded with the very Type I crystals he says were the result of the recrystallization.

F. Even If Watson's Boiling Water Procedure Were A Legitimate Experiment, Its Results Are Invalid Because Material 1 Was Seeded With Type I Crystals

Seeding is a shortcut. Persons of skill can purposely seed an experiment by adding small crystals of the form they want, rather than waiting for the solution to nucleate on its own and grow the crystals the hard way. TT630:23-631:16 (Myerson). But seeding need not be purposeful, and can involve the inadvertent contamination of a crystallization solution with a crystal form. TT643:8-644:10 (Myerson). Regardless of how seeding occurs, once a crystal seed is present that crystal seed's form is the type of crystal the solution will generate. TT630:23-631:16 (Myerson). Because Dr. Rogers' starting material contained some amount of Type I crystals already, his efforts to "recrystallize from boiling water" are meaningless.

Dr. Myerson determined that there was a Type I crystal seed in Dr. Rogers' starting material because when he examined its x-ray powder diffractogram ("XRPD"), he saw a large, defined peak at 6.5. TT649:9-650:5. The peak at 6.5 is the characteristic peak for the Type I polymorph because

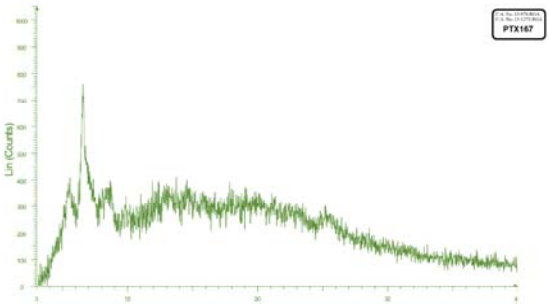
Type I is the only known polymorph that has a peak at 6.5. TT450:16-22 (Rogers). In order to confirm his results, Dr. Myerson analyzed the data that Dr. Rogers provided with XRPD software. TT650:11-16. He found all of the characteristic peaks of Type I within ±0.2 degrees 2-theta of those listed in the '168 Patent. TT653:5-11.

Watson disputes Dr. Myerson's findings, especially taking issue with the parameters that he chose in order to analyze the data. Yet at least Dr. Myerson did an analysis. Dr. Rogers never did a computer peak search analysis of Material 1, despite having done one with all the other XRPD data he generated in this case—data in which he was trying to find Type I crystals.[9] TT441:11-442:5, 450:23-451:4, 452:3-11 (Rogers). And as the Court might have expected, Watson's brief does not talk about what Dr. Marsden concluded.

Watson hired Dr. Marsden to synthesize calcium 5-methyl-(6S)-tetrahydrofolate (Dr. Rogers' Material 1) and perform an analysis to determine whether Material 1 was amorphous. TT537:13-21. Watson requested that Dr. Marsden perform an XRPD of Material 1, and that Dr. Marsden put his interpretation of the powder x-ray on the certification of analysis for Material 1. TT541:6-24. Dr. Marsden did the analysis, and generated an XRPD. But Watson withheld from Dr. Marsden the '168 Patent and the XRPD for the Type I crystal with its 100% intensity peak at a 2-theta angle of 6.5. TT557:5-10, 557:22-558:7. Thus, the XRPD that Dr. Marsden first interpreted for Watson and his report did not scan below a 2-theta angle of 10; through no fault of his own but because Watson did not give him complete information. TT556:2-7, 558:14-21; PTX158.

[9] Dr. Rogers' conclusory statement that the peak at 6.5 is "not uncommon for calcium salts of long molecules" is not credible and is unsupported by any evidence in the record. TT259:7-9.

Dr. Marsden first saw the full XRPD for Material 1 at his deposition. PTX167 (right). He acknowledged that when he finally saw the full XRPD of Material 1, that "amorphous substances generally don't display a sharp peak like the one you see at around 6.5 here." TT560:2-9; PTX167. Despite the fact that he did not "do this all the time,"[10] Dr. Marsden admitted that he did not hesitate in determining this XPRD did not show a fully amorphous material. TT560:2-561:6.



III. CLAIM 4 IS NOT OBVIOUS

The Court may recall the Principles of Polymorphism. TT460-463 (Rogers), 612-613 (Myerson). The undisputed testimony from both Dr. Rogers and Dr. Myerson is that finding an as yet undiscovered polymorph is an unpredictable process of trial and error. TT465:2-23 (Rogers), 612:23-613:7 (Myerson). There can be no reasonable expectation of success sufficient to make a patent obvious when trial and error is necessary. *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 555 F. App'x 961, 971 (Fed. Cir. 2014) (finding that invention was "complicated, unpredictable, and largely conducted through trial and error" precluded finding of reasonable expectation of success (internal quotation marks omitted)); *In re Armodafinil*, 939 F. Supp. 2d at 497 (finding no reasonable expectation of success where "a skilled artisan would have expected to resort to trial and error experimentation"). Watson's only answer is to rely on the same flawed analysis of the '850 Patent and boiling water procedure from its anticipation analysis. Def. Br. 28. The '850 Patent example cannot give a person of skill a reasonable expectation of success in generating the Type I crystal

[10] Watson made an unbecoming effort to explain away Dr. Marsden's XRPD opinion by attacking its own expert's qualifications. Watson never questioned Dr. Marsden's qualifications until after his deposition. TT538:20-543:18. The evidence shows that Dr. Marsden is qualified to interpret XRPDs in the manner Watson originally requested of him. TT661:6-10 (Dr. Myerson confirms that Dr. Marsden is at the level of ordinary skill in the art of the '168 Patent). Dr. Marsden has interpreted XPRD in both his doctoral thesis and peer-reviewed literature. TT532:18-534:11.

because it does not disclose the Type I crystal (nor its characteristic 2-theta values), does not contain real data of any kind, does not necessarily and always produce the Type I crystal when its procedure is performed, and is in fact inoperable and not enabled.

Even ignoring Watson's failure to show a reasonable expectation of success, the unrebutted evidence shows that a person of ordinary skill would not have chosen the prolonged slurry heating described in the '168 Patent that is essential to producing the Type I crystal in the face of the known thermal instability of calcium 5-methyl-(6S)-tetrahydrofolate. PTX5; TT662:16-664:9 (Myerson). Watson provided no response to Dr. Myerson's opinion and the Barrett article (PTX5). Watson instead falls back on the same four words from the '850 Patent that are the sum and substance of its technical invalidity case: "recrystallized from boiling water." Recrystallized from boiling water does not mean prolonged high temperature heating and there is no evidence in this case that, without seeding, Type I can be obtained from any boiling water recrystallization.[11]

IV. CLAIM 4 IS NOT INVALID FOR LACK OF WRITTEN DESCRIPTION

Watson's written description argument is that the '168 Patent allegedly fails to describe one specific embodiment contained within the genus of Claim 4: the monohydrate form Watson says is impossible to produce. This is contrary to the law of written description and, in addition, factually inaccurate. The law does not require that a patent expressly describe every embodiment within the scope of the claim. *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) ("A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language."). Even accepting Watson's factual proposition as true (which it is not), that would not result in Claim

[11] As both Dr. Myerson and Dr. Rogers testified, there are a considerable number of choices a person of skill must make in performing a recrystallization further demonstrating the true trial and error nature of even practicing the single step of a "recrystallization." TT465-474 (Rogers), 638-641 (Myerson).

4's invalidity for lack of written description.

Watson is also wrong on the facts. Claim 4 is limited on its face to Type I crystals having at least one water of crystallization. The specification states that "[c]rystalline calcium salts of 5-methyltetrahydrofolic acid have a content of water of crystallisation of at least 1 equivalent of water per 1 equivalent of 5-methyltetrahydrofolic acid. Thus the Type I modification typically contains ≥3 equivalents of water …." DTX2 at 2:12-16. The patent examples of Type I crystals describe water content of at least 1 equivalent of water. *Id.* at Examples 7, 9. Claim 4, therefore, claims what the specification describes—Type I crystals having at least one water of crystallization.

Watson's written description argument is also internally inconsistent and self-defeating. As Dr. Rogers testified at length, under his theory a person of ordinary skill would understand that Claim 4 is limited to a Type I crystal (TT487:20-488:17, 492:15-21), and also understand from the specification that Type I is limited to hydrates having more than one water because monohydrate forms are not possible (TT489:3-9, 489:18-23, 491:11-24, 492:22-493:7). Therefore, what a person of skill would understand is covered by the claims is identical to what that person would understand is described by the patent—there is nothing left in the claim undescribed in the specification. Watson's argument contradicts itself.

CONCLUSION

For the foregoing reasons, the Court should enter judgment in favor of Plaintiffs.

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CERTIFICATE OF SERVICE

I hereby certify that on July 2, 2015, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on July 2, 2015, upon the following in the manner indicated:

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